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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,740	10/09/2003	Ronald D. Berger	2784-36	8147
23117	7590	09/22/2006	EXAMINER	
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			SMITH, TERRI L	
			ART UNIT	PAPER NUMBER

3762

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/681,740

Applicant(s)

BERGER, RONALD D.

Examiner

Terri L. Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10-09-03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: On page 14, in line 11, it appears that the word “directing” should perhaps be the word “directly” instead.

Appropriate correction is required.

Claim Objections

2. Claim 12 is objected to because of the following informalities: The phrase “where the quasi-Faraday cage at least one of” is unclear as written. It is suggested to add either the word “is” or “comprises” after the word “cage.” Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the Applicant regards as his invention.

4. Claims 7–9 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In claim 7, the phrase “the quasi-Faraday cage is not an active element in a shock circuit” is vague. It is unclear how the quasi-Faraday cage is not an active element in the system, but the system sets forth in claim 4 that it is meant to apply shocks.

In claims 8 and 13, the phrase “a significant portion” is vague and indefinite. It is unclear how much a significant portion is. Applicant has not defined a significant portion in the specification nor does the specification given any indication that a significant portion is associated with any specific dimension.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1–9 and 11–12 rejected under 35 U.S.C. 102(e) as being anticipated by Alferness et al., U.S. Patent 6,169,922.

7. Regarding claims 1, 4, 8, and 12, Alferness et al. disclose an implantable cardioverter defibrillator (ICD) system (Fig. 8, element 106) comprising: a quasi-Faraday cage (Figs. 3, 3A, 4, 4A, element 10, jacket) including only a single electrode (column 10, lines 19–21) and electrodes (Fig. 8, elements 101 and 101a); wherein a single electrode and electrodes of a quasi-Faraday cage is adapted to be wrapped around at least about 50% and a significant portion and 60% of a heart during application of electric shock to a heart (Figs. 4, 4A, element 10, jacket where Examiner interprets the jacket to encompass the majority of the claimed limitations); a quasi-Faraday cage at least one of: (b) squeezes heart muscle that it is wrapped around in order to improve cardiac function (column 10, lines 40–44).

8. With respect to claims 2, 3, 5 and 6, Alferness et al. disclose a single electrode of the quasi-Faraday cage is adapted to be wrapped around at least 60% (claims 2 and 5) and 70% (claims 3 and 6) of a heart during application of electric shock to a heart (Figs. 3, 3A, 4, and 4A where Examiner interprets the jacket (10) in these figures to encompass the majority of the limitations as set forth in the claimed invention).

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9. Regarding claims 7, 9 and 11, Alferness et al. disclose, a quasi-Faraday cage is not an active element in a shock circuit which applies a shock to a heart (claim 7) (Figs. 3, 3A, 4 and 4A; column 7, lines 61–62; column 8, line 46); a single electrode of a quasi-Faraday cage comprises a mesh of conductor provided on or in a flexible fabric (claim 9) (Fig. 6; column 10, lines 19–21); a quasi-Faraday cage squeezes heart muscle that it is wrapped around in order to improve cardiac function (claim 11) (column 10, lines 40–44).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alferness et al., U.S. Patent 6,169,922 and in view of Heilman et al., U.S. Patent 4,030,509.

12. With respect to claim 10, Alferness et al. disclose the essential features of the claimed invention except for an electrode of a quasi-Faraday cage is used to perform a heart pacing function to alter ventricular activation sequence and improve cardiac function. However, Heilman et al. disclose an electrode of a quasi-Faraday cage is used to perform a heart pacing function to alter ventricular activation sequence and improve cardiac function (ABSTRACT, lines 25–34) because of its close proximity to the heart, the electrode permits easy detection of cardiac signals by and ICD such that optimum analysis of the electrical activity of the heart can be performed and the appropriate therapy administered when required. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have

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modified the invention of Alferness et al. to include an electrode of a quasi-Faraday cage is used to perform a heart pacing function to alter ventricular activation sequence and improve cardiac function, as taught by Heilman et al. to enhance and improve signal monitoring and therapy administration of an ICD system.

13. Regarding claim 13, Alferness et al. disclose an implantable cardioverter defibrillator (ICD) system for applying electric shock to a heart of a patient (Fig. 8, element 106), an ICD system comprising: a quasi-Faraday cage including a plurality of electrodes (Fig. 8, elements 101 and 101a); wherein electrodes of a quasi-Faraday cage is adapted to be wrapped around a significant portion of a heart during application of electric shock to a heart (Fig. 8). Alferness et al. do not disclose means for adjusting current density applied to a plurality of electrodes of a quasi-Faraday cage, so that different currents flow through different electrodes of a quasi-Faraday cage. However, Heilman et al. disclose means for adjusting current density applied to a plurality of electrodes of a quasi-Faraday cage, so that different currents flow through different electrodes of a quasi-Faraday cage (column 9, lines 9–12 where Examiner interprets connection of the electrodes to the two different sets of electronics to encompass different current flow through different electrodes) to provide a diverse and multipurpose ICD system. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Alferness et al. to include means for adjusting current density applied to a plurality of electrodes of a quasi-Faraday cage, so that different currents flow through different electrodes of a quasi-Faraday cage, as taught by Heilman et al. to provide a diverse and multipurpose ICD system.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1–13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1–4 of U.S. Patent No. 6,633,780. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims are more narrow and therefore, meet the limitations of the broader application claims. Additionally, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include in the patent claims a single electrode, the quasi-Faraday cage at least one of (a) performs a heart pacing function to alter ventricular activation sequence and improve cardiac function and (b) squeezes heart muscle that it is wrapped around in order to improve cardiac function, and means for adjusting current density applied to a plurality of electrodes of a quasi-Faraday cage, so that different currents flow through different electrodes of quasi-Faraday cage, since it is well-known in the art to use a single electrode to perform a

defibrillation therapy and to use a quasi-Faraday cage to perform a heart pacing function to alter ventricular activation sequence and improve cardiac function to ensure efficient and safe defibrillation therapy and to squeeze heart muscle that it is wrapped around in order to improve cardiac function to protect the heart muscle during defibrillation therapy, and means for adjusting current density applied to a plurality of electrodes of a quasi-Faraday cage, so that different currents flow through different electrodes of quasi-Faraday cage to provide a diverse and multipurpose ICD system.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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TLS

September 15, 2006

15 September 2006



GEORGE R. EVANISKO
PRIMARY EXAMINER

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